

Remarks

Claims 1–34, 58, 59, 73, 79, 80 and 82–90 are pending in the application and are rejected as allegedly being unpatentable over U.S. Patent No. 6,183,780 to Van Balken *et al.* (Van Balken) in view of U.S. Patent No. 6,120,803 to Wong *et al.* (Wong). Applicant thanks Examiners Oh and Gollamudi for the courtesy of the telephone interview on October 20, 2003, and for suggesting the foregoing claim amendments to place the claims in condition for allowance.

Applicant maintains that the claims as pending in the application prior to entry of the present amendment are allowable for at least the following reasons: (1) The Office failed to establish a *prima facie* case of obviousness because there is no suggestion or motivation to combine or modify Van Balken and/or Wong to produce applicant's claimed tablets; (2) the combination of Van Balken and Wong destroys each of their intended functions and thus the references are not properly combinable; and (3) even if the references are properly combined, no combination of Van Balken and Wong results in applicant's claimed tablets.

Nonetheless, solely to expedite prosecution, applicant has requested that claims 1, 73, 79, 83, 85 and 88–90 be amended to clarify that the claimed belly band includes at least one active ingredient. Specifically, claim 1 as amended states that the belly band comprises "the at least one active ingredient." Claims 73 and 79 as amended recite "a belly band comprising the active ingredient," and claims 83, 85 and 88–90 have been amended to recite a "belly band comprising the at least one active ingredient." Thus, the independent claims now clarify, as requested by the Examiners, that the belly band comprises an active ingredient.

In response to the Examiners' suggestion, claims 1, 73, 79, 83, 85 and 88–90, which feature an outer rupturable coating or rupturable membrane, have been amended to recite that rupture occurs in the gastrointestinal tract. Support for these amendments can be found on, for example, page 15, lines 24–29. Gastrointestinal rupturing can be determined by *in vitro* methods as discussed in the specification and as specifically described in Example 3, pages 22–24.

The Examiners requested that applicant explain the purpose of an enteric coating material as recited in claim 13, wherein the rate release modifying membrane overcoats the enteric coating material. Briefly, such layering of an enteric coating material and the rate release modifying membrane provides additional useful formulation methods of drug release profile control. For example, the enteric coating material provides another method for influencing both

the lag time and the amount of time that the support platforms remain attached to the drug releasing tablets. By, for example, modifying the amount of time that the support platforms remain attached to the tablet, drug release from the core can be modified. Typically, the enteric coating material diminishes the time that the support platforms remain attached to the tablet, thus accelerating drug release. Thus, the enteric coating materials provide another method for varying the drug release profile exhibited by the claimed tablets.

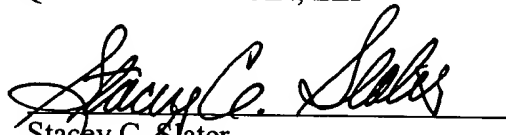
Moreover, the drug release profile can be further influenced by varying the composition of the enteric coating material. For example, typically, enteric coating materials dissolve at a pH-dependent rate, commonly dissolving more quickly in intestinal fluids than gastric fluids. However, enteric coating materials also can be low solubility materials that dissolve only slowly in intestinal fluids. Additionally, varying amounts and mixtures of enteric coating materials can be used to vary the properties of the coating.

Conclusion

Applicant again thanks Examiners Oh and Gollamudi for granting applicant's representatives a telephone interview on October 20, 2003, and for suggesting the foregoing claim amendments. According to the agreement reached during the October 20, 2003, interview, applicant understands that the foregoing amendments place the application in condition for allowance. Such action is respectfully requested.

Respectfully submitted,

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